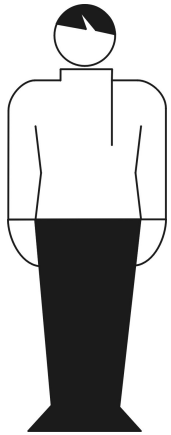
***A**nthrax*
***V**accine*
***I**mmunization*
***P**rogram*

Protecting
the Individual



7 Dec 99

Background on Anthrax

- Recognized as an illness for centuries
- Spores can survive in soil for decades
- Once common where livestock were raised
- Animal anthrax controlled with a vaccine for livestock
- Human infection usually results from direct contact with infected animals or animal products

Anthrax

- Anthrax is a known biological weapon.
- Inhalational anthrax is highly lethal.
- Vaccination against anthrax is critical for
  your protection.
- This is a mandatory vaccination program,
  except for legitimate medical exemptions.

Threat

- Anthrax: the most likely Biological Warfare agent:
  - Easy and cheap to produce
  - Spores make an effective biological weapon
  - Can be stored for a long time
  - Can be dispersed in air by a variety of weapons
  - Inhalational anthrax is highly lethal
  - Odorless, colorless, tasteless, difficult to detect
- Anthrax will cause widespread illness and death among unprotected personnel.

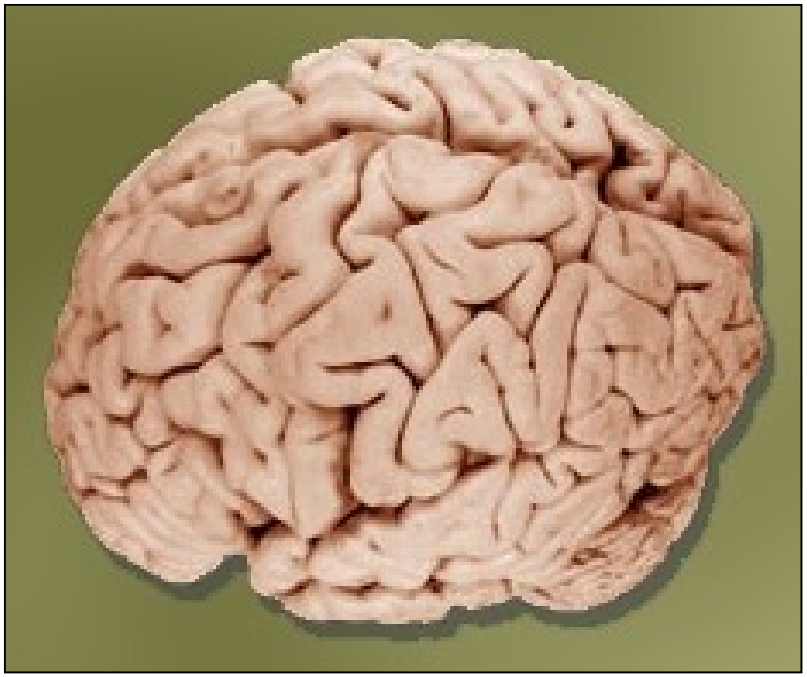
Anthrax: Three Disease Types

- Skin (Cutaneous) Anthrax
  - 95% of natural cases; spores enter skin breaks
  - Responds well to antibiotics… 1 in 5 die if untreated
- Gastrointestinal Anthrax
  - Ingestion (e.g., eating undercooked, infected meat)
  - Severe GI symptoms… 50% may die even with treatment
- INHALATIONAL ANTHRAX
  - "Flu-like symptoms" early, rapid deterioration, and death
  - Mortality may exceed 80% after symptoms occur, despite treatment

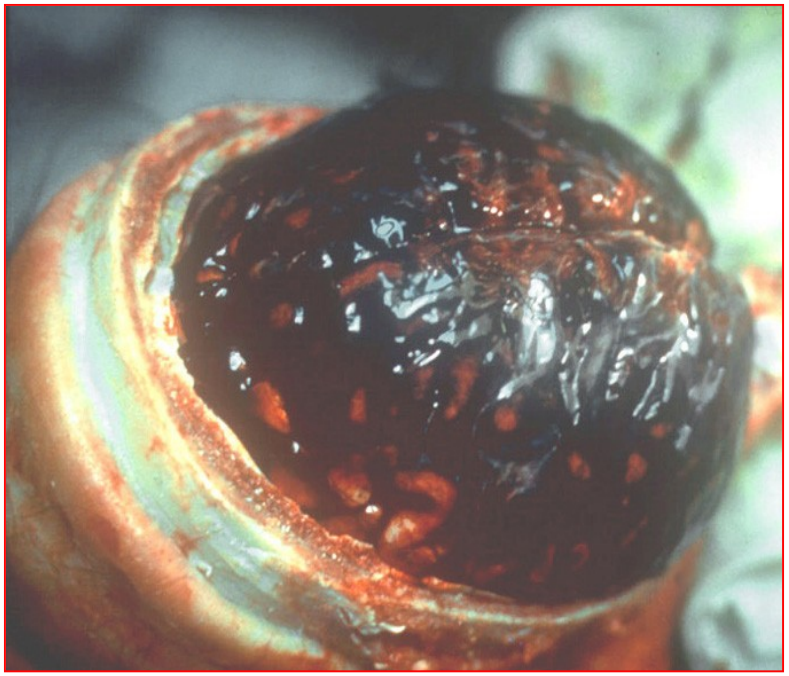
Inhalational Anthrax

- Inhalational anthrax occurs when spores enter the body through the lungs
- Not transmitted person to person
- Spores migrate to lymph system where bacteria multiply and produce lethal toxins
- Toxins cause bleeding and destruction of the brain or vital organs in the chest, resulting in death

The Human Brain



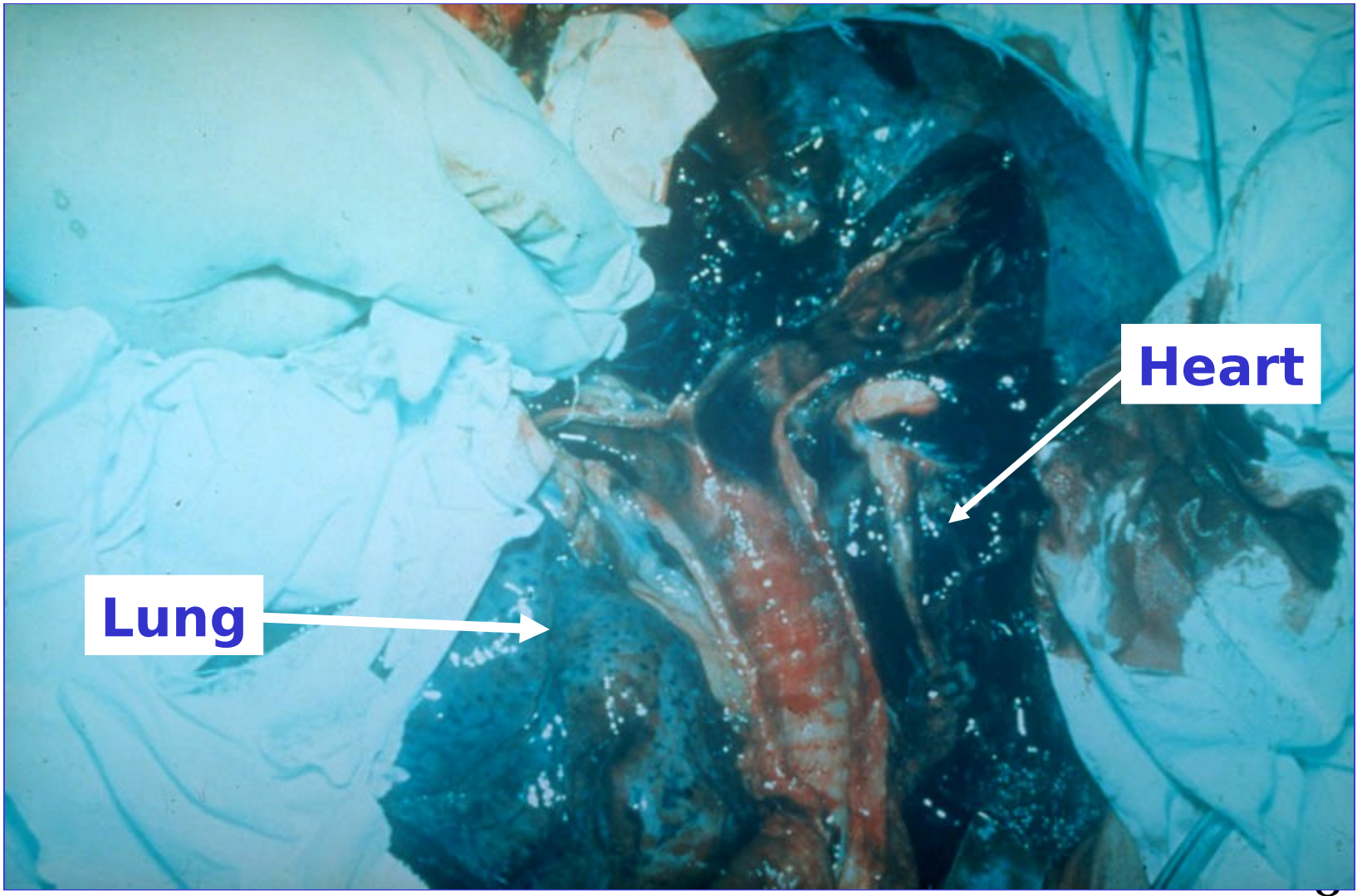
Normal Brain



Brain of a person who died from inhalational anthrax

Note that the usually clear fluid which surrounds the brain becomes bloody from the anthrax infection.

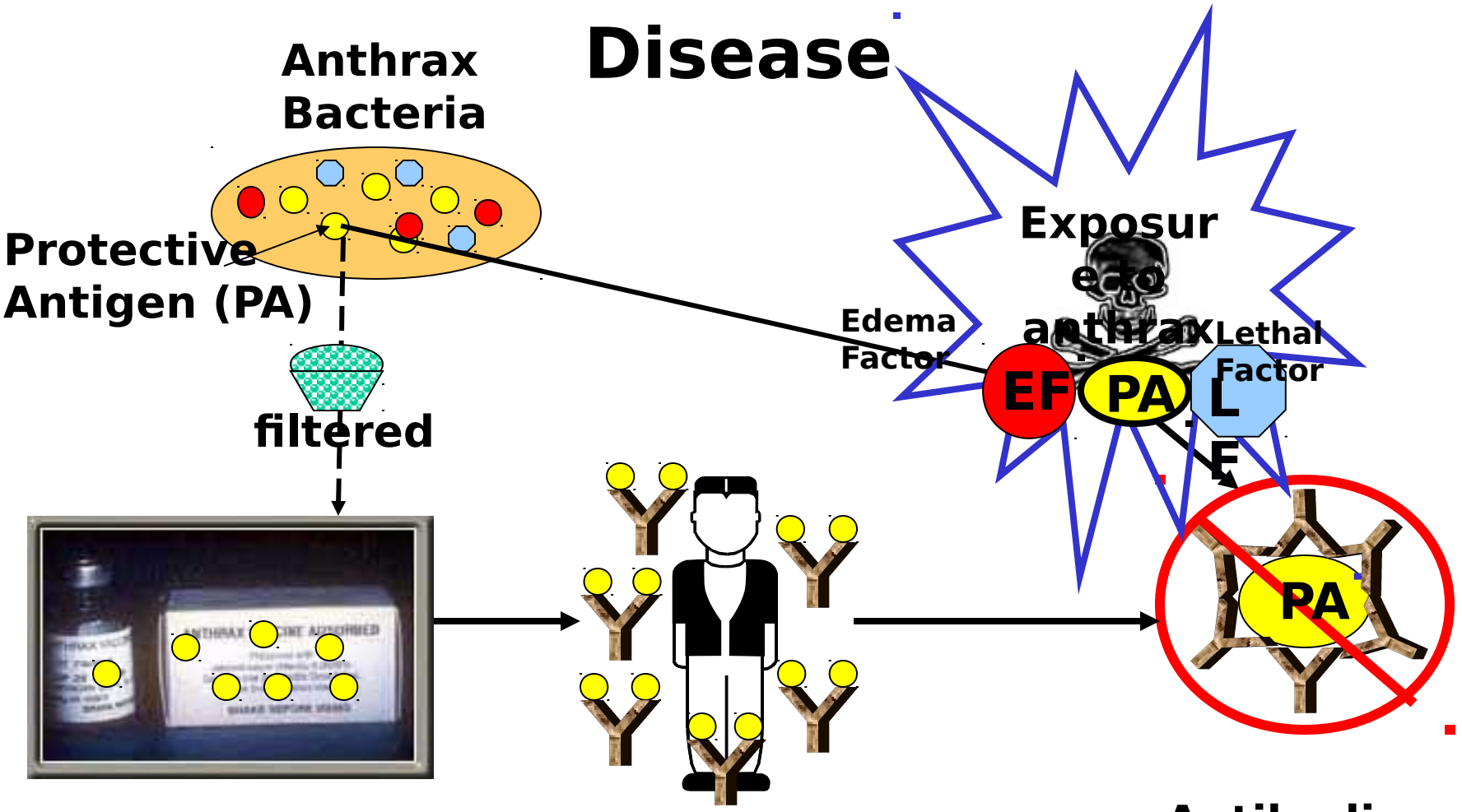
Inhalational Anthrax Victim (view of chest cavity)



Anthrax Vaccine

- Licensed by the FDA since 1970
  - Safely administered in the U.S. to at-risk veterinarians, laboratory workers, and livestock handlers
- No whole or live anthrax bacteria
  - Contains protective antigen (PA)
  - Cannot cause anthrax disease
- Manufactured in U.S. by BioPort Corporation
  - Lansing, Michigan
- Dosing schedule: 0, 2, 4 weeks, 6, 12, 18 months, plus annual boosters

How Anthrax Vaccine Prevents Disease



Vaccine contains PA, extracted from anthrax bacteria.

Immune system develops antibodies (Y) to PA, protection from disease.

Antibodies "neutralize" PA, common part of anthrax toxins.

Response to Vaccination

- Anthrax vaccine, like other vaccines, stimulates your body to produce protective antibodies
- The full series is needed to obtain maximum and on-going protection
- Even with a good antibody response, your defense system can be overwhelmed, given a massive number of spores. Use your mask too.

Vaccine Protection Against Different Strains

- Vaccine efficacy demonstrated against numerous anthrax strains (types) in animal studies
- Protective antigen is the common disease-causing protein in all anthrax strains
- Therefore, anthrax vaccine protection is expected against all strains

Injection-Site Reactions

- From Hawaii, Korea, Ft. Bragg, Ft. Detrick, 1993-99: Redness, itching, swelling (lasting a few days)
  - Less than 1 inch: men up to 30%, women up to 60%
  - 1 to 5 inches: 1% to 5%
  - Greater than 5 inches: up to 1%
  - Swelling may extend below elbow
- Soreness or local pain in 8% to 19%
- Lump: 30% to 90% (may persist a few weeks)
- Women report reactions more often than men

Systemic Events

(Events Away from the Injection Site)

- From 5% to 35% will notice:
  - – Muscle aches, joint aches, chills, low-grade fever,

    no appetite, headaches, nausea, malaise, related

    symptoms
  - – Women report these symptoms more often than men
  - – These symptoms usually go away in a few days, less

    than a week

Injection-Site Reactions and Systemic Events

- Ask your health care provider whether ibuprofen, acetaminophen, antihistamines, or other medications may help reduce bothersome symptoms.
- Report adverse events after vaccination to health care provider promptly, before additional vaccinations.

Adverse Event Reporting

- Vaccine Adverse Event Reporting System (VAERS)
  - FDA reviews 100% of adverse-event reports submitted to either FDA or DoD
  - Anyone can submit a Form VAERS-1
- DoD requires a Form VAERS-1 submission for:
  - Loss of duty greater than 24 hours
  - Hospitalization
  - Suspected vaccine vial contamination
- Other submissions permitted
- Form VAERS-1 may be obtained from:
  - 1-800-822-7967/ www.anthrax.osd.mil/vaers/vaers.htm

Reserve Component Adverse-Event Guidance

- An individual experiencing a vaccine-associated adverse event in a non-duty status:
  - Seek medical evaluation at a DoD, USCG, or civilian medical treatment facility, if necessary
  - Must report the event to your unit commander or designated representative as soon as possible
  - See local medical department or squadron for guidance
- Commander will determine Line of Duty and/or Notice of Eligibility status, if required

Long-Term Studies

- More than 1,500 Fort Detrick laboratory workers vaccinated against anthrax
  - Followed for up to 10 - 20 years
  - None developed unexplained symptoms due to repeated doses of anthrax vaccine or any other vaccines they received
  - Employees followed annually
- Additional studies are underway to gather more information

Air Crew Issues

- Federal Aviation Administration Federal Air Surgeon states in letter dated 15 Oct 99:

  "individuals who have been immunized with the anthrax vaccine are not disqualified from performing civilian airman duties so long as they do not experience significant side effects that would otherwise be considered disqualifying."

- Independent research conducted by Virtual Flight Surgeons
  - www.aviationmedicine.com

Air Crew Myths and Facts

(www.aviationmedicine.com)

- ***Rumor:*** The FAA will revoke my medical certificate if I receive the anthrax vaccine.
- **Facts.** FAA Aeromedical Certification Division confirms that anthrax vaccination does not affect a pilot's medical certificate. Pilots do not even have to report receipt of any vaccine on their FAA medical application.
- ***Rumor:*** Airlines won't hire me or will terminate me if I take the anthrax vaccine.
- **Facts.** Airline medical directors contacted confirmed that anthrax vaccination has no effect on hiring or retention decisions. Several corporate policies encourage pilots to comply with military preventive-medicine programs.

Air Crew Myths and Facts

(www.aviationmedicine.com)

- ***Rumor:*** Medical insurance carriers drop coverage for conditions resulting from the anthrax vaccine.
- **Facts.** Medical insurance carriers are required by law to provide coverage for non pre-existing conditions arising from legitimate treatment. Anthrax vaccine is FDA-licensed for human use.
- ***Rumor:*** Company will not authorize paid sick leave or disability for complications from the anthrax vaccine.
- **Facts.** Corporate medical directors contacted by VFS physicians indicated that any legitimate medical condition that interferes with safe flying or medical certification is covered for sick leave and disability per contract terms.

Key Messages

- Anthrax used as a biological weapon represents a grave and urgent threat to U.S. Armed Forces

- Weaponized anthrax is as lethal as the Ebola virus
  - once symptoms develop, death is > 99 percent certain in unvaccinated, untreated individuals

- We have a safe and effective vaccine, licensed by the FDA, to protect against the deadly threat of anthrax weapons

Information Sources

- Chain of command
- Http://www.anthrax.osd.mil
- Http://www.defenselink.mil
- Http://www.cdc.gov
- Http://www.aviationmedicine.com
- Call Toll Free 1-877-GET-VACC
  (1-877-438-8222)